October 20. 2000
Mr. Fu Sheng Jin
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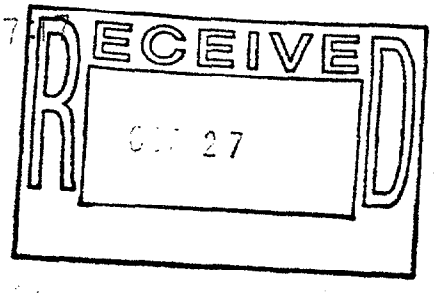

Dr. Elizabeth Yetley
Office of Special Nutrition
HFS-450
200 C Street, S. W.
Washington, D. C. 20204

Dear Dr. Elizabeth Yetley:

According to " Dietary Supplement Health and Education Act of 1994" Public Law 103-417, Now I write a petitioner about Yu Han Ren Brand Seabuckthorn oil softgel(dietary supplement) to notice of structure/ function class for 30 days post-market. Also I want to get permission to import to the United States of America .Although it has been delivered to the United State of America before October 15, 1994, we need to revise the" Seabuckthorn oil softgel" labeling again.

SEabuckthorn oil softgel
Manufactured by Inner Mongolia Kedi High-Tech Industrial Co., Ltd, Huhhot, China
10 Yiwei Road, Ruyi Economic and Technological Development Zone,
Huhhot, Inner Mongolia, China

Distributed by Chinese Herb Center, Inc.

I included following data for Seabuckthorn oil softgel for you check it, If you have any questions, Please tell me or write a letter to above address.

Sincerely Yours
Fu Sheng Jin
Manager Mr. Fu Sheng Jin

LET 6141
73105

975-0162

A petitioner to FDA about Yu Han Ren brand Seabuckthorn Oil softgel

A. Identity; Composition; Physical, Chemical and Organoleptic Characteristics

1. Name of Dietary supplement
   a. Chemical name: not available
   b. Common name: Seabuckthorn Oil
   c. CAS registry number: not available

2. Chemical identity:
   a. Structure formula: not available
   b. Molecular weight: not available
   c. Molecular formula: not available

3. Organoleptic properties:
   a. Appearance: powder
   b. Color: light brown yellow oil
   c. Taste: not sour

4. Physical and Chemical properties:
   a. pH: ND
   b. Melting point: ND
   c. Water content: ND
   d. Solubility: soluble in water.
   e. Specifications:

Seabuckthorn oil extract is manufactured by Inner Mongolia Kedi High-Tech Industrial Co.,LTD. They sent the samples of Seabuckthorn oil softgels (the batch number LB-19-9701050272) for analysis, and they received the data from the Strasburger & siegel, Inc., Analytical and Consulting Services 7249 National Drive Hanover, Maryland 21076. The following data measured per softgels are listed below.

(1) Content:

(a) Average amount of impurities, toxins and pesticides in one of softgel of the Seabuckthorn extract oil

Heavy metal	Lead (Pb)	6.0 ppb
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<30 ppb
Others	Nitrite	ND
	Nitrate	ND

(b) Other toxins
Aflatoxins (B1, B2, G1, G2): contains less than 10 ppb in samples of Seabuckthorn extract oil.
Mycotoxin: ND

(c) Contaminated pesticides: No

The amount of impurities and toxins measured are lower than that specified in the FDA food standard.

(2) Components:
The Seabuckthorn oil extract per 100g contains Linoleic acid 35-38g, Linolenic acid 27-32g, Oleic acid 20-26g, Vitamin E 70-220IU, Vitamin A 1500-2200 IU, Carotene 60-80mg, Total flavonoids 10-60mg, phytoesterol 1-1.3g, etc.

Method of measurement used in above tests:

1. Official Methods of Analysis (1995), 16th ED., AOAC International, Gaithersburg, MD
2. Laboratory Information Bulletin No. 3640 (toxin Elements), Determination of the low levels
   of lead in foods by Graphite Furnace Atomic Absorption, U.S. Food and Drug Administration,
   Washington, DC
3. Bacteriological Analytical Manual (1995), 8th ED., U.S. Food and Drug Administration,
   Washington, DC
4. Compendium of methods for the Microbiological Examination of Foods (1992), 3ed., APHA,
   Washington, DC

All data have been certified by the STRASBURGER & SIEGEL, INC. Job NO 005-10-139-04/04
All nutritional indexes of method numbers have been referenced from " the methods of analysis for nutrition labeling," 1995 by AOAC INTERNATIONAL.

B. Intended use; projected average daily intake of Seabuckthorn oil softgel:

1. Amount of Seabuckthorn oil softgel proposed use in the United States
Projected marketing figures for Seabuckthorn oil softgel have not been determined at this time.

2. Intended usage
Seabuckthorn oil softgel is intended for use as a natural dietary supplement for essential unsaturated fat acid .

3. Calculation of expected intake and daily consumption of Seabuckthorn oil softgel:
From information given by Inner Mongolia Kedi High-Tech Industrial Co., Ltd, the seabuckthorn oil softgel is to be taken three times a day, two softgels each time. Each softgel weights 500mg of seabuckthorn oil, and this projects a daily consumption of 3.0g and yearly consumption of 1095g for an adult.

4. Labeling

Supplement Facts

Serving Size: 1 softgel

INGREDIENTS:

Each capsule contains Seabuckthorn oil 5000 mg.
Linoleic acid 37.5%*
Linolenic acid 29.5%*
Oleic acid 23%*
Phytoesterol 1.5%*
Total flavonoids 35 mg*
Vitamin E 145 IU*
Vitamin A 1850 IU*
Carotene 70mg*

***is calculated by (per 100g)**

Daily values not established
Other ingredients:
gelatin capsule

Keep out the children
Store at a cool & dry location
Batch No:

Yu Han Ren Brand

100% Natural Herbs Dietary

Seabuckthorn Oil

80 Softgel (500 mg each)

The statement has not been approved by the Food & Drug Administration. This product is not intended to diagnosis, treat, cure, or prevent any disease.

Manufactured by Inner Mongolia Kedi High-Tech Industrial Co., Ltd. Huhhot, China

Introduction
it has been formulated by Inner Mongolia Kedi High-Tech Industrial Co., Ltd. Huhhot, China. It is a special dietary supplement for essential unsaturated fat acid. It is modified and refined by modern technology. It is an unique process and guaranteed potencies. Any questions about dosage and questions, please consult your physician or TCM doctor or call 202-393-1203.

Recommended use:
Orally, take 2 softgels each time
2-3 times a day, after meal with water.

Distributed by Chinese Herb Products, Inc.
1010 Vermont Ave, NW Suite 712,
Washington, DC 20005

Lot:

Expire date:

C. Safety investigations (toxicological studies)

1. Overall toxicity:

In a series of medical books, Such as the Rgyudi bzi in the 8th century and Chinese pharmacopoeia, 1977, seabuckthorn was recorded in detail as traditional medicines for moistening lung and being good for asthma in breath system, coordinating the balance of functions among liver, stomach, spleen kidney and heart(TCM term), serving to assuage pain caused by wounds and promotion healing and regeneration of blood circulation and elimination of blood stasis in circulation system, keeping young and improving energy, protecting from cancer and lowing lipid. The Ministry of Health, People Republic of China has considered it as a food-stuff as well as a medical plant without toxicity or side effect. Now this treatment has been kept till today and its efficacy is further improved by modern scientific studies. (See reference). With the advanced supercritical carbon dioxide extractive technique, Yu Han Ren seabuckthorn oil is extracted from fine seabuckthorn seed of the Manhan Mountains, which is one of the three most famous seabuckthorn species of China. The product contains abundant unsaturated fat acids, vitamin trace elements and carotene. It has been approved as health food by the Ministry of Health as grade AA green food by China Green Food Development Center.

It is manufactured with an unique process that preserves and concentrates the richest extract of fresh herb. Already there are over millions people in the world taking seabuckthorn oil extract every day. Also seabuckthorn oil softgel is delivered to many parts of the world, such as Europe, Africa, America, Canada and Australia, etc., and people's responses to this product have been extraordinary due to its effectiveness and safety. Also it has been delivered to the United States of America before October 15, 1994. Therefore it is considered as GRAS.

According to reports based on research experiments using 5% alcohol extracts derived from two hundred selected varieties of commonly used medicinal herbs, include the components of seabuckthorn oil softgel. when said, extracts were forced to male white mice using the Linchofield and Wilcoxon method in order to determine the LD 50 of each herb, the conclusive results showed that the average LD50 was 2,000-5,000 milligrams, with the exception of raw Radix Aconniti Kusenezoffii and Semen Strychni. Thus, for most commonly used medicinal herbs and formulas, the safe dosage was found to be relatively high: for a person weighting 50 kilograms, LD 50 was approximately 250 grams; when take in normal dosage, most medicinal herbs have almost no toxicity(see reference 1). The recommended usage for seabuckthorn oil is 3g per day; this dosage does not present any safety concerns According to acute toxic test and long term test, they can not determine LD50 dosage in mice and Wistar big mice.

2. Acute toxicity test for seabuckthorn oil

Animal species: Little white mice, Kun ming species of average weight 30g, is supplied by Department of animal , the Pharmaceutical Department of Xian Medical University in Shannnxi Province . The acute toxicity test has been done by the same unit.

(a) 60 Little white mice are divided three groups, each group has 20 mice. Control group mice are fed for water; another two group are fed for low dose(30ml/KG.BW) and high dose(60ml/Kg.BW). The acute toxicity experiment proved that the first time ingestion of 15ml and 30ml/KG.BW in seabuckthorn oil for 20 mice. after 6 hour, continuingly each group mice received another dosage 15ml/Kg, and 30ml/KG.BW. Total each mice received low dose 30ml/Kg.BW and 60 ml/Kg.BW of seabuckthorn oil. after observe one week, they don't find any mice death. At the first day, most mice presents with diarrhea and appetite decrease. the rest six days, every mice is normal activity, has no diarrhea and normal appetite. therefore they can not measure LD50 in mice. After 8th day, they do autopsy, the result show that there are no significant difference comparison to control group; there are no pathological change in heart, liver spleen, lung, kidney and brain in the experimental group mice.

(b) In the second part of acute toxic experiment in Wister big mice, Wister species of average weight 140+/-10g, half male, and half female, 30 mice is divided three groups, each group has 10 mice. 10 control group mice are fed water; another two groups mice are fed

seabuckthorn oil for low dose(10ml/KG.BM) and high dose(20ml/Kg.BW). The acute toxicity experiment proved that the first time ingestion of 5ml and 10ml/KG.BW in seabuckthorn oil for 10 mice. after 6 hour, Each group mice received another dosage 5ml/Kg, and 10ml/KG.BW. after observe one week, they don't find any mice death. At the first day, some mice appetite decrease and daily activity decrease. the rest six days, every mice is normal activity. therefore they can not measure LD50 in mice.

(c) In the third part of long term toxic experiment in Wister big mice, Wister species of average weight 140+/-10 g ,half male, half female, total 80 wister big mice. They continue to feed each mice for 90 days, 80 Wister big mice are divided into three group for experiment and another group for control. each group contains 20 mice, Control mice received water, experimental group mice received 2ml/Kg.BW, 5ml/Kg,10ml/Kg.(equal to 12,30,60 time of human clinic dosage). After observing for 90 days, There are no death, hair growth and behavior change in the three groups; there is no significant difference comparison by control group ($p>0.05$), also they do the blood teat including HB, RBC, WBC count+DC platelet, all the blood test are in the normal range, There is no significant difference comparison by control group mice ($P>0.05$).

They also do the blood index test, including ALT, BUN, all test results are in the normal range, there is no significant difference comparison to control group mice ($P>0.05$). There are no pathological change in the heart, liver lung spleen, kidney, brain, adrenal gland, testis, oval gland, thymus gland, all organ weight are in the normal range, there is no significant difference comparison to control group mice($P>0.05$)

The dosages in the three group used in the toxicity studies are equivalent to 12,30,60 times of clinic dosage (3g/day)in human. Therefore they can not get LD50 in Wistar mice.

3. Impurities, byproducts(limits):

Heavy metal	Lead (Pb)	6.0 ppb
	Arsenic (As)	ND
	Cadmium (Cd)	ND
	Mercury (Hg)	<30 ppb
	Nitrite	ND
	Nitrate	ND
Other toxins	Aflatoxin B1,B2,G1,G2	<10 ppb
	Mycotoxin	not to be found

No contaminated pesticides such as 666 and DDT in 30 sample of seabuckthorn oil.

4. Microbiological examination of seabuckthorn oil: <3 MPN E.Coli/g

Reference:

1. Dr. William Chang: " Reference guide of commonly used herbal formilas". 1989.
2. Official Methods of Analysis(1995),16th Ed., AOAC International, Gaithersburg, MD
3. Bacteriological Analytical Manual (1995), 8th Ed., U.S. Food and Drug Administration, Washington,DC
4. Compendium of method for the Microbiological Examination of Foods (1992), 3rd Ed., APHA, Washington,DC
5. Laboratory Information Bulletin No. 3640 (toxic Elements), Determination of low levels of lead in foods by Graphite Furnace Atomic Absorption, U.S.Food and Drug Administration, Washington,DC

E. Proposed tolerances

No tolerances are required to insure the safety of seabuckthorn oil, because of its non-toxic nature.

F. Environmental Assessment

1. Date: October 20, 2000

2. Name of Petitioner: Chinese herb Center, Inc.

3. Address of Petitioner:
   1010 Vermont Ave, NW Suite 712
   Washington DC 20005
   Tel: (202)393-1203

4. Introduction of seabuckthorn oil softgel into Environment

The seabuckthorn oil softgel is manufactured in China for importation into the United States. It is consumed in small quantities in households across the country, under no circumstances this capsule will cause any environmental pollution when discarded by consumer. The capsule is packaged in transparent gelatin capsule, and there are no direct or indirect additives or irradiated herbs used in seabuckthorn oil softgel. The amount of seabuckthorn oil softgel consumed or discarded in any one area will generate no toxicity and will have no impact on the local waste treatment system.

The seabuckthorn oil softgel is manufactured in Inner Mongolia Kedi High-Tech Industrial Co Ltd, China. The manufacturer states that their manufacturing process does not result in the emission of any pollutants of concern, and the process does no harm to the environment. The manufacturing process is carried out in conformance with all Chinese laws covering environmental safety, and product number for this product is to be granted by the Chinese government.